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FOR #1 PTO-1 (REV 12-29-9		ATTORNEY'S DOCKET NUMBER							
TI	RANSMITTAL LETTER	TO THE UNITED STATES	T2328-906561						
	DESIGNATED/ELECT	ED OFFICE (DO/EO/US)	U.S. APPLICATION NO (If known, see 37 CFR 1.5)						
	CONCERNING A FILIT	NG UNDER 35 U.S.C. 371	09/601106						
	ATIONAL APPLICATION NO. GB99/00288	INTERNATIONAL FILING DATE 28 January 1999	PRIORITY DATE CLAIMED 30 January 1998						
TITLE OF INVENTION PREPARATION FOR TREATMENT OF ERECTILE DYSFUNCTION									
APPLICA Coli	ANT(S) FOR DO/EO/US n Anthony KEMP								
Applican	t herewith submits to the United State	s Designated/Elected Office (DO/EO/US) the follow	owing items and other information:						
1.		s concerning a filing under 35 U.S.C. 371.							
2.		NT submission of items concerning a filing under							
3.	This express request to begin nation examination until the expiration of	al examination procedures (35 U.S.C. 371(f)) at ar	ny time rather than delay						
4.	examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.								
5.		lication as filed (35 U.S.C. 371(c)(2))							
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		the International Bureau.							
6.		pplication was filed in the United States Rece l Application into English (35 U.S.C. 371(c)(
7.		e International Application under PCT Article							
		(required only if not transmitted by the Inter							
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!	 1	wever, the time limit for making such amend	ments has NOT expired.						
	d. have not been made and		•						
8. 🔲	A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).								
9.	An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).								
10.	A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).								
Items 1	11. to 16. below concern docume	nt(s) or information included:							
11.		ment under 37 CFR 1.97 and 1.98.							
12.		ording. A separate cover sheet in compliance	with 37 CFR 3.28 and 3.31 is included						
13.	A FIRST preliminary amendmen								
	A SECOND or SUBSEQUENT								
14.	A substitute specification.	neminiary amendment.							
15.	A change of power of attorney as	nd/or address letter.							
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16.	Other items or information: 1	. Correspondence Address ar Without Declaration	nd Notice of Filing						
	2.Verified Statement Small Business Cond	Claiming Small Entity: Independent	pendent Inventor and						
	3. Claim for Priority 4. Information Disclos	sure Statement, w/PTO form 14	449						
	5.International Search								
	6. International Pres	liminary Examination Report							
	Abstract	on of Application (Spec. 6 pg							
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BASIC NATION Neither intern nor internatio	lowing fees are submitted: AL FEE (37 CFR 1.492 (a) ational preliminary examina nal search fee (37 CFR 1.44 anal Search Report not prepare	\$970.00						
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Independent claims	4 -3 =	1	X \$78.00	\$ 39.00				
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b. Please o	 a. A check in the amount of \$849.00 to cover the above fees is enclosed. b. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed. c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1165 . A duplicate copy of this sheet is enclosed. 							
NOTE: When 1.137(a) or (b) SEND ALL CORRE Dennis P. Miles & S. 1751 Pinn	re an appropriate time limit) must be filed and granted spondence to: Clarke Stockbridge nacle Drive, Suite	it under 37 CFR 1.494 or 1.49 d to restore the application to	pending status. SIGNATU Denn:	met, a petition to re				
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Attorney's Docket No:

Applicant or Patentee:
Serial or Patent No:
Filed or Issued:
For:
VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(b)) INDEPENDENT INVENTOR As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under
Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled: PREPARATION FOR TREATMENT OF ERECTILE DYSFUNCTION
described in
The specification filed herewith.
D Application Serial No. , filed .
Patem No, issued
I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).
Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:
No such person, concern, or organization
Persons, concerns or organizations listed below*
*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention avarring to their status as small entities. (37 CFR 1.27).
FULL NAME: FUTURA MEDICAL LIMITED
ADDRESS: Antrobus House, 18 College Street, Petersfield, Hampshire GUIS 4AD VI

Signature of Inventor

FULL NAME:							
ADDRESS: _							
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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VE ST/	RIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY ATUS (37 CFR 1.3 (0 AND 1.27 (c)) - SMALL BUSINESS CONCERN
I hereby declare the	atlan:
() the (X) ser	owner of the small business concern identified below: official of the small business concern empowered to act on behalf of the concern identified below:
· N 2	AME OF CONCERN: FUTURA MEDICAL LIMITED
·	DDRESS OF CONCERN: Antrobus House, 18 College Street, Petersfield,
and remained in that the number of statement (1) the persons employed affiliants of each of	Hampshire 6013 4AD UK rat the above identified small business concern qualifies as a small business concern as defined in 13 CFR 1213-18. 37 CFR 1.9(d), for purposes of paying induced fees under Section 41 (a) and (b) of Title 35. United States Code, in a complayers of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this a number of employees of the business concern is the average over the previous fiscal year of the concern of the long full-time, part-time or temperacy losis during each of the pay periods of the fiscal years, and (2) concerns are other when either, directly or indirectly, one concern controls of has the power to control the other, or a third party or has the power to control both.
with regard to the	hat rights under contract or law have been conveyed to and remain with the small business concern identified above a invention entitled * * " by inventor(s) KEMP. C. A. described in REPARATION FOR TREATMENT OF ERECTILE DYSFUNCTION a specification filed herewith the filed term in the polication No filed issued
	the above identified small business concern are exclusive.
I acknowledge the	e duty to file, in this application or putent, notification of any change in status resulting in loss of entitlement to spring or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date or small entity is no longer appropriate. (17 CFR 1.28(b))
are believed to be	that all statements made herein of my own knowledge are true and that all statements made on information and belie is true; and further that these statements were made with the knowledge that willful false statements and the like at ble by fine or imprisonment, or both, under Sentian 1801 of Title 18 of the United States Code, and that such willful may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verifies ted.
NAME OF PE	RSON SIGNING: KEMP, Cölin, Anthony
TITLE OF PE	RSON OTHER THAN OWNER: Managing Director
	PERSON SIGNING: 18A Beechworth Road Havant, Hampshire PO9 1AX, UK
BATE.	SIGNATURE

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PREPARATION FOR TREATMENT OF ERECTILE DYSFUNCTION

This invention relates to a preparation for topical application to the male sexual organ, especially for the treatment of erectile dysfunction.

Erectile dysfunction is a widespread problem with human males, albeit not commonly discussed in public. It is not regarded as a medical condition susceptible to treatment in the conventional sense being to a large extent caused by a mental condition or at least exacerbated by a loss of confidence following an initial experience caused perhaps by tiredness or an over-indulgence in food or alcohol. Nevertheless, the consequences are serious to the sufferer, resulting in psychological damage and in many cases frustrating the normal fertilisation processes so that artificial insemination procedures must be used if procreation is required. Procedures for overcoming this problem have been proposed which can involve the surgical implantation of stiffening devices as described in GB-A-1476804, US-A-5242391 and other patents. Chemotherapeutical approaches have been proposed which require the injection of vasodilator compositions immediately prior to intercourse. The injection takes place on or near the penile shaft. Neither procedure is attractive and both approaches can result in revulsion or distress on the part of the partners involved. US-A-5059603 and US-A-4801587 propose topical application of compositions containing vasodilators. US-A-5059603 proposes the use of a composition including a combination of a vasodilator and vasoconstrictor in a carrier intended to assist absorption of the active ingredients through the skin of the penis, the active ingredients being chosen so that the

vasodilator acts more quickly than the vasoconstrictor whereby an erection of the penis. having been initiated by the action of the vasodilator, is sustained by the action of the vasoconstrictor. Vasodilators said to be appropriate for use in such compositions include nitroglycerin, papaverine, hydralazine, sodium nitroprusside phenoxybenzamine, among others. Vasoconstrictors include caffeine. 3-(2-aminoethyl)indole derivatives and adrenaline. US-A-4801587 proposes a composition in the form of an ointment and including a vasolidator selected from papaverine, hydralazine, sodium nitroprusside, phenoxybenzamine and phentolamine mixed in a base with dimethylsulfoxide as a skin-absorption agent. Dimethylsulfonide is also proposed for the same purpose in US-A-5059603.

It has now been found that nitroglycerin (glyceryl trinitrate) can be used as a vasodilator in a composition for topical application to the penis in conjunction with carrier materials without either a vasoconstrictor or dimethyl sulfoxide, which is known to be a toxic material, and that such compositions are effective for the treatment of erectile dysfunction.

According to one aspect of the present invention, there is provided the use of a combination of compounds in the preparation of a composition for the treatment of erectile dysfunction in human males, the compounds comprising glyceryl trinitrate and lanolin.

According to another aspect of the invention, a method of treatment of erectile dysfunction in males comprises applying to the penis a composition comprising an effective amount of glyceryl trinitrate and lanolin, and causing or permitting the composition to penetrate the skin of the penile shaft.

The carrying our of the method of the invention before sexual intercourse results in an erection of the penis which not only enables subsequent intercourse to take place but also provides for the subject male a mental state of renewed confidence in his ability as a sexual partner and may provide for the other partner a sense of relief from any self-doubt concerning her abilities to stimulate her partner to a state of sexual arousal. The method according to the invention is thus a means of acquisition of a particular state of mental well-being or a method of enhancing or promoting sexual appeal or sexual confidence, with cosmetic overtones in terms of enhancing the appearance of the male anatomy in the circumstances of intimate sexual activity.

The invention also includes, in a further aspect, the use of glyceryl trinitrate and lanolin in the treatment of erectile dysfunction in human males.

The glyceryl trinitrate acts as a vasodilator according to its established utility for example in the treatment of angina pectoris but it has not hitherto been recognised that

in simple combination with lanolin there could be provided an effective treatment of erectile dysfunction in human males.

Glyceryl trinitrate is a material which is per se explosive. For use in the present invention, it is preferably adsorbed on a solid stabilizer in finely-divided particulate form, the particles being in the sub-micron size range to render them capable of passage through the skin. A preferred stabilizer compound is lactose on which the glyceryl trinitrate may be adsorbed at a concentration of from 5 to 20% by weight, for example 10% by weight. Glyceryl trinitrate is preferably present in a concentration up to 5% by weight of the overall formulation; a concentration of 1% or 2% by weight is generally sufficient to be effective.

The lanolin acts as a lubricant or moisturiser and also enhances skin absorption. It is known to be non-toxic and for the purpose of the present invention should be used as a medical grade such as "Medilan" (Trade Mark).

Preferably, compositions according to the invention also include a physical stabilizer such as a paraffin cream; optionally, the compositions contain other ingredients such as fragrances and/or colorants. The paraffin cream, for example provided as White Soft Paraffin B.P., promotes stability of the composition on the skin and also acts as a water-repellant barrier and lubricant.

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The composition also includes water to adjust the overall viscosity or consistency and concentration of the active ingredient to the desired levels, bearing in mind that for ease of use the composition should be in the form of a physically-stable suspension of the active ingredient in a creamy emulsion which is sufficiently low in viscosity to be readily applied to and spread over the skin of the penis at ordinary body temperatures.

An example of a composition for use according to the present invention is given below:

Ingredient	Weight %
Glyceryl trinitrate (10% in lactose)	10
Lanolin ("Medilan")	44
White Soft Paraffin B.P.	21
Demineralized Water	25

In use, two grams of the above formulation, which has the form of a white cream, was applied to the glans penis and penile shaft and gently massaged into the skin. The effect was to produce an erection of the penis which was sustained for approximately 45 minutes. The effect in producing an erection way be enhanced by other stimuli of tactile, audio and/or visual nature.

The formulation may be used in conjunction with a condom, in which the formulation is applied to the penis and a condom applied in the usual manner after an erection has been attained. Condoms suitable for use with the formulation are preferably of the non-latex type, for example formed from polyurethane.

CLAIMS:

- 1. Use of a combination of compounds in the preparation of a composition of for the treatment of erectile dysfunction in human males, the compounds comprising glyceryl trinitrate and lanolin.
- 2. A method of cosmetic treatment for improving the bodily appearance of human males, the method comprising applying to the penis a composition comprising an effective amount of glyceryl trinitrate and lanolin, and causing or permitting the composition to penetrate the skin.
- 3. A method of treatment of erectile dysfunction in males comprises applying to the penis a composition comprises an effective amount of glyceryl trinitrate and lanolin, and causing or permitting the composition to penetrate the skin of the penile shaft.
- 4. The use of glyceryl trinitrate and lanolin in combination as a cosmetic product.
- 5. The use as claimed in claim 1 or claim 4, or a method of cosmetic treatment as claimed in claim 2 or claim 3, in which the glyceryl trinitrate is adsorbed on a solid stabilizer in finely-divided particulate form.

7. The use or the method according to claim 6, in which

the glyceryl trinitrate is adsorbed on the lactose at a concentration of from 5 to 20% by weight.

- 8. The use or the method according to any preceding claim, in which the glyceryl trinitrate is present in a concentration up to 5% by weight.
- 9. The use or the method according to any preceding claim, in which the composition also includes a physical stabilizer.
- 10. The use or the method according to claim 9, in which the composition also includes water.
- 11. The use or the method according to any preceding claim, in which the composition consists essentially of 10wt% glyceryl trinitrate (10% in lactose), 44wt% lanolin, 21wt% white soft paraffin B.P. and 25wt% demineralized water.
- 12. The use of a composition as claimed in claim 1 in conjunction with a condom.
- 13. In combination, a composition as defined in claim 1 and a condom.

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant

Colin Anthony KEMP

International

Application No.:

PCT/GB99/00288

International

Filing Date

28 January 1999

Serial No.

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For

PREPARATION FOR TREATMENT OF ERECTILE

DYSFUNCTION

Filed

CORRESPONDENCE ADDRESS AND NOTICE OF FILING WITHOUT DECLARATION

Hon. Commissioner of Patents & Trademarks Washington, D.C. 20231

Sir:

This application is being filed on behalf of **Colin Anthony KEMP**, without an executed Declaration. After appropriate notification from the U.S. Patent and Trademark Office, a duly executed Declaration will be submitted:

Please address all communications relative hereto as follows:

Dennis P. Clarke 1751 Pinnacle Drive

Suite 500

McLean, VA 22102

U.S.A.

Tel:

(703) 903-9000

Fax:

(703) 610-8686

Respectfully submitted,

Dennis P. Clarke

Registration No. 22,549

DPC/maa

Combined Declaration for Patent Application and Power of Attorney (Cominsed)								72328-906561		
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